REMARKS

Claims 1-57 are pending in the present application. Applicants amend claims 1, 21, 27-33, 43, 45, 46, 49, and add new claims 51-57, as shown above. Support for the amendments and the new claims can be found, e.g., on page 5, lines 15-20, page 8, lines 14-17, in the original claims and throughout the remainder of the specification. Thus, no new matter is added.

Rejections Under 35 U.S.C. 112

The Office Action rejects claims 21, and 28-32 as being indefinite. In response, these claims are amended, as discussed below, to overcome these rejections.

In particular, claim 21 is amended, as shown above, to remove the recitation of the preferred wavelength ranges for each depth (these preferred ranges are re-introduced in new claim 56).

Further, claims 28-30 are amended to recite that the *foci* provided by the *optical system* are separated so as to generate a particular ratio of treatment portion to a volume in which the treatment portions are disposed, thereby presenting specific features of the optical system.

Moreover, claims 31 and 32 are amended to further recite that the *foci* are configured such that the selected portions within the volume, to which radiation is directed, have specific shapes.

Rejections Under 35 U.S.C. 102(b)

The Office Action rejects claims 1-5, 7, 9-14, 16-21, 23, 24, 26-31, 37, 39, 40, and 43-49 as being anticipated by U.S. Patent No. 6,050,990 of Tankovich.

Claim 1, as amended, recites a method for performing a treatment on a volume located at an area and depth coordinates of a patient's skin that includes providing a radiation source, and applying radiation from that source to an optical system that provides multiple foci for concentrating the radiation to at least one depth within the depth coordinate and to selected areas within the area coordinate of that volume. The depth and the selected areas in which the

radiation is concentrated define *three-dimensionally located treatment portions* that are *separated* from one another by *untreated portions*.

Tankovich relates to methods and apparatus for applying laser light to a subject's skin for modulating hair growth. A plurality of light-absorbing chromophore particles are applied to a skin area such that at least a portion of the contaminant particles enters the upper regions of the hair follicles in that area. A beam of light having a small spot size is *rapidly scanned* over the area such that at each illuminated location, the beam – by virtue of its small spot size – generates a steep energy gradient within the skin below that location. Tankovich asserts that this gradient can result in a differential heating of the top and the bottom portions of the illuminated particles, with the heating at the top causing a small explosion for propelling the particles downward into lower regions of skin. Once the particles are spread into the base of the hair ducts by the propulsion laser pulses, a larger diameter laser beam is employed to heat them and hence the tissue surrounding the hair duct. With reference to FIGURE 16A of Tankovich, in another embodiment, rather than switching between a small and a larger diameter laser beams, a mask having pinhole apertures is employed to split a larger diameter pulsed beam into a plurality of smaller diameter beams suitable for generating a steep gradient. The mask is "shifted slightly at random" to *even out* illumination over the entire area containing the particles. *See* Tankovich, col. 19, lines 30-32. Alternatively, the mask is replaced with array of lenses to generate a plurality of small beams for propelling the particles into the lower regions of the skin.

Tankovich does not teach or even suggest utilizing an optical system that provides multiple foci to apply radiation to three-dimensional *treatment* portions *separated from one another* by *untreated* portions. In Tanknovich, even though the mask (or the lens array) generates a plurality of small beams that provide a pattern of illuminated and unilluminated areas, the mask is *moved randomly* in order to ensure that the entire area to which the particles are applied is illuminated. This is consistent with the need to propel the particles over the *entire* area, and not only in specific portions thereof, into the lower regions of the skin. Moreover, the radiation of the skin by a plurality of small beams is intended to propel the particles into the lower regions of the skin, and *not* to provide any treatment. In contrast, claim 1 expressly recites that the radiation is concentrated into three dimensional treatment portions separated from one another by untreated portions.

Hence, claim 1 and claims 2-5, 7, 9-14, 16, 20, 21, 23, 24, 26, 47 and 48, which depend either directly or indirectly on claim 1, are patentable over Tankovich.

The arguments presented above apply with equal force to establish that independent claim 17, directed to a method for performing a treatment on a volume located within a patient's skin, is also patentable over Tankovich. In particular, Tankovich fails to teach at least one material feature of claim 17: applying radiation to an optical system having a plurality of foci which concentrates the radiation into a plurality of treatment portions disposed within untreated portions of a volume requiring treatment. Further, claims 18 and 19 depend on claim 17, and hence are also patentable.

Claim 27, as amended, recites an apparatus for performing a treatment on a volume located at area and depth coordinates of a patient's skin that includes a radiation source, and an optical system to which radiation from that source is applied. The optical system provides a plurality of foci for concentrating the radiation to at least one depth in that volume and to selected areas of that volume, which define three-dimensional treatment portions within untreated portions of that volume. The apparatus further includes a controller for *selectively activating* the source so as to *successively* irradiate the plurality of foci. Support for amendments to claim 27 can be found at page 10, line 26 to page 11, line 5, pages 25 and 26 as well as throughout the remainder of the specification, including FIGURE 22B. Thus, no new matter is added.

Although Tankovich discloses an array of lenses (See FIGURE 16B) for transforming an incident large beam received from a radiation source into a plurality of small beams for delivering radiation to the skin, it does not teach or suggest a controller that would selectively activate the source for successive irradiation of the lenses. On the contrary, in this embodiment of Tankovich, all of the lenses are simultaneously irradiated by a large beam. Hence, Tankovich fails to teach or suggest at least one feature of claim 27. Accordingly, claim 27 and claims 28-31 37, 39 and 40, which depend either directly or indirectly on amended claim 27, are patentable.

Claim 43, as amended, recites an apparatus for performing a treatment on a volume located at area and depth coordinates of a patient's skin that includes a radiation source, and a mechanism which cools the patient's skin over the area coordinate to a selected temperature. The apparatus further includes controls for selectively operating the mechanism to precool the skin for a selected duration before, and/or during, application of radiation. The mechanism and controls apply cooling for a duration sufficient to cool the skin to a temperature below normal body temperature and to at least a depth below the depth coordinate. The apparatus further includes an optical system including *multiple foci* to which radiation from said source is selectively applied. The optical system concentrates the radiation to a depth in the volume and to selected areas of that volume to define treatment portions, where the treatment portions are less than the total volume. And each treatment portion is substantially surrounded by untreated and cooled skin. The optical system further comprises a controller for *successively directing the radiation to the multiple foci*.

Tankovich does not teach a system having a multi-focal optical system that includes a controller for successively directing radiation from a source to the multiple foci – features of claim 43 and claim 44 that depends on claim 43.

Claim 45, as amended, recites a method for performing a therapeutic treatment on a patient's skin by utilizing a multi-focal optical system to concentrate applied radiation of selected wavelength at a plurality of three-dimensionally located, treatment portions, which treatment portions are *separated from one another by* non-treatment portions.

The arguments presented above apply to establish claim 45 also distinguishes patentably over Tankovich. In particular, as discussed in detail above, Tankovich does not teach creating treatment portions that are separated from one another by non-treatment portions.

Claim 46, as amended, recites an apparatus for performing a therapeutic treatment on a patient's skin. The apparatus comprises a multi-focal optical system for concentrating applied radiation of selected wavelength at a plurality of selected, three-dimensionally located, treatment portions, which treatment portions are within non-treatment portions. The optical system further includes a controller for successively directing the applied radiation to the treatment portions.

As discussed above, Tankovich does not teach a multi-focal system having a controller for successively directing applied radiation to a plurality of treatment portions disposed within non-treatment portions.

Similar arguments apply to establish that claim 49 is also patentable over Tankovich as it recites, among other features, directing radiation to treatment portions within a volume requiring treatment such that each treatment portion is surrounded by an untreated portion of that volume.

The Office Action rejects claims 1, 6-13, 15-18, 27-34, 36-39 and 41-47 as being anticipated by U.S. Patent No. 5,885,211 of Eppstein.

Eppstein, which is directed to transdermal delivery of drugs to the body, does not teach treating a volume of skin by concentrating radiation onto treatment portions within that volume that are *separated from one another by untreated portions*. Rather, Eppstein relates to a method of increasing the permeability of the skin through formation of microporations (small holes or pores) in the stratum corneum – a waterproof membrane that provides a barrier against entry of external substances and outward migration of fluids and dissolved molecules. In one embodiment, a light-absorbing topical compound is applied to the skin, and is illuminated by radiation that heats the compound to an elevated temperature. The heated compound raises the local temperature of the stratum corneum, via heat conduction, to a sufficiently elevated level that results in ablation and hence formation of micropores. The spectral content of the illuminating radiation and its focusing are selected such that the radiation would not be significantly absorbed by the tissue, and would sufficiently diverge as it penetrates deep into tissue to further inhibit significant absorption.

The micropores generated in Eppstein are not three-dimensional treatment portions as recited in claim 1, but are rather micro-conduits that facilitate drug delivery. Further, as discussed above, the radiation employed for generating them is chosen to have minimal interaction with the skin tissue itself. In addition, there is no indication in the passage cited by the Examiner, or in any other portion of Eppstein, that the optical system focuses radiation only on selected regions of the portion of the skin to which the topical substance is applied. In fact,

such a selective illumination of the topical substance would be counter-productive as it reduces the efficiency of micro-pores production.

Further, U.S. Patent No. 4,775,361 cited in Example 28 of Eppstein, to which the Examiner refers, discloses the use of excimer laser radiation to remove the stratum corneum (the top layer of the skin) for facilitating percutaneous transport of therapeutic substances. It does not teach treating the skin, much less generating treatment portions within a volume at a depth of a patient's skin that are surrounded by untreated portions.

Hence, claim 1 and claims 6-13, 15, 16, 47 and 48 that depend on claim 1, distinguish patentably over Eppstein.

The same arguments apply with equal force to establish that claim 17, and claim 18 that depends on claim 17, also distinguish patentably over Eppstein. In particular, similar to claim 1, claim 17 recites separating the treatment portions from one another via untreated portions of the skin – a feature not taught by Eppstein.

Further, Eppstein fails to teach or suggest salient features of the apparatus recited in claim 27. For example, it does not teach a controller for selectively activating a radiation source *so as to successively* irradiate a plurality of foci provided by an optical system receiving the radiation. Thus, claim 27, and claims 28-3, 37-39, 41 and 42 dependent on claim 27, distinguish patentably over Eppstein.

As noted above, Eppstein does not teach a multi-focal optical system, a feature of the apparatus of claim 43. Further, claim 44 depends on claim 43.

Moreover, Eppstein fails to teach salient features of claim 45 such as concentrating radiation at a plurality of treatment portions that are separated from one another by untreated portions.

Further, unlike claim 46, Eppstein does not teach a multi-focal optical system having a controller for successively directing radiation to three-dimensional treatment portions in a patient's skin, which are separated by untreated portions.

The Office Action rejects claims 49 and 50 as being anticipated by U.S. Patent No. 4,653,495 of Nanaumi.

Claim 49, as amended, recites a method of treating a patient's skin that includes providing a radiation source, and directing radiation from that source to a plurality of spatially separated three-dimensional treatment portions disposed in a selected volume of the patient's tissue requiring treatment such that different treatment portions are irradiated sequentially over time such that each *treatment portion is surrounded by an untreated portion* of the volume. The treatment portions comprise a fraction of the volume ranging from *about 10% to about 50%.*

Nanaumi is directed to a laser medical apparatus that includes a hand piece in which a plurality of optical fibers having square cross-sections are disposed. A scanning unit can successively supply radiation from a laser to the input end face of each fiber, which transmits the radiation, through a transparent protective cover coupled to the output end of the hand piece, to the diseased spot. Nanaumi indicates that the scanning of the diseased spot by laser beams radiated through the optical fibers ensures a *uniform* treatment of the diseased spot. *See* col. 7, lines 6-10.

Nanaumi does not teach generating treatment portions within a diseased spot such that each treatment portion is surrounded by an untreated portion, and hence it does not teach a particular fill factor of such treatment portions (percentage of a treatment volume occupied by the treatment portions). Rather, it describes irradiating a diseased spot uniformly, albeit by irradiation of different portions by a plurality of fibers.

Accordingly, claim 49, and claim 50 that depends on claim 49, distinguish patentably over Nanaumi.

Rejections Under 35 U.S.C. 103(a)

The Office Action rejects claims 1, 22, 27, 36 and 38 as being obvious in view of the combined teachings Tankovich of U.S. Patent No. 5,000,752 of Hoskin.

Hoskin is directed to an apparatus for treating port wine stains that includes a plastic pad in which a plurality of needle assemblies, each of which is coupled by an optical fiber to a laser assembly, are disposed. Each needle assembly includes a support body held captive in the strip as well as a needle element that engages the support body and a conical diamond or sapphire tip. The needle element includes a hollow tube that receives the end portion of the fiber for optically coupling light received from the laser assembly to the conical tip, which in turn generates a desired radiation profile for irradiating a treatment area. In operation, the pad is pressed down over the area requiring treatment to cause the tips of the assemblies penetrate the upper layer of the skin to a desired depth. The tips would then generate *overlapping* radiation patterns for treating the area causing the port wine stains. Alternatively, the port wine stain can be treated in a two-step process in which a pattern of selected areas is treated in an initial step followed by treating a pattern of areas intervening those treated in the initial step. In this manner, the entire area of the port wine stain is treated.

Although Hoskin's apparatus includes a pattern of needle assemblies, each separated from another by a distance, Hoskin's does not teach utilizing its apparatus to generate a plurality of treatment portions that are *separated from one another by untreated portions.* Rather, it teaches irradiating the *entire* treatment area. For example, as discussed above, the tips of the needle assemblies are configured such that their generated radiation patterns are *overlapping* so as to treat the entire port wine stain area; or, alternatively, the entire area is irradiated by multiple applications of radiation to intervening patterns of treatment areas. Hence, Hoskin does not teach a material feature of the claimed invention (i.e., separation of treated portions by untreated portions in a treatment volume) and its associated advantages - such as, more efficient healing of a treatment portion.

Further, Tankovich fails to bridge the shortcomings of Hoskin. In particular, as discussed in detail above, Tankovich fails to teach treating a volume of a patient's skin by

generating therein a plurality of treatment regions that are separated from one another by untreated portions of that volume.

Thus, claim 1, and claim 22 that depends on claim 1, distinguish patentably over the combined teachings of Hoskin and Tankovich.

With regard to claim 27, neither Tankovich nor Hoskin teaches a controller for selectively activating a radiation source to successively irradiate a plurality of foci for concentrating radiation onto a plurality of treatment portions disposed within untreated portions of a skin volume requiring treatment. In fact, as noted above, Hoskin's apparatus provides overlapping radiation patterns for illuminating an entire treatment area. Further, claims 36 and 38 depend either directly or indirectly on claim 27, and hence incorporate the patentable features of this claim.

The Office Action rejects claims 1, 6-8 and 35 as being obvious in view of the combined teachings of Nanaumi and Tankovich.

As discussed above, in Nanaumi, an *entire* diseased spot, rather than selected portions thereof, is irradiated by radiation from a laser source, albeit via illumination of different portions by a plurality of optical fibers. That is, unlike claim 1, Nanaumi does not teach generating a plurality of treatment portions within the diseased spot that are separated from one another by untreated portions. Further, Tankovich fails to bridge the shortcomings of Nanaumi because as discussed in detail above, it fails to teach or suggest treating a volume of skin by irradiating treatment portions therein that are separated from one another by untreated portions.

Thus, claim 1, and claims 6-8 that depend on claim 1, distinguish patentably over the combined teachings of Nanaumi and Tankovich.

With regard to claim 35, which depends on independent apparatus claim 27, neither Tankovich nor Nanaumi teaches a controller that can be employed for successively irradiating a plurality of treatment portions disposed within untreated portions of a volume.

New Claims

Support for new claims 51-57 can be found at page 5, lines 5-22, page 10, line 26 to page 11, line 5, pages 25 and 26, in the original claims, as well as the remainder of the specification. Thus, no new matter is added.

The new claims distinguish patentably over the cited references. In particular, none of the references teaches focusing radiation sequentially over time onto selected treatment regions within a volume requiring treatment such that each treatment region is separated from other treatment regions by untreated tissue of that volume, as recited in new claim 51 and consequently in claims 52-55 that depend on claim 51. Further, new claim 56 depends on claim 20, and further recites wavelength ranges for particular depths.

New claim 57 recites a method of treating a patient's skin by irradiating a plurality of spatially separated three-dimensional portions within a volume of the skin requiring treatment for a dermatological condition such that each irradiated portion is surrounded by a non-irradiated portion. The irradiated portions comprises a fraction in a range of about 10% to about 30% of the volume.

None of the cited references teaches treating a volume skin that suffers from a dermatological condition by employing fractional irradiation, i.e., irradiating selected portions that are separated from one another by non-irradiated portions, much less teaching a specific range of the volume of the irradiated portions relative to the entire volume requiring treatment. Further, although U.S. Patent Application No. 6,059,820 of Baronov, which was cited in the previous Office Action, discloses an embodiment in which a plurality of copper stripes, disposed at the end of a radiation-transmitting rod, block light from reaching portions of skin, it does not teach or suggest the fractional volume of the irradiated portions recited in claim 57. In particular, the recited fractional volume of about 10% to about 30% can be particularly efficacious as it provides a significant non-irradiated fractional volume while ensuring that sufficient fraction of the volume is irradiated to effect the desired therapeutic response in the entire volume.

Hence, new claim 57 is also patentable.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully request reconsideration and allowance of the application. Applicants invite the Examiner to call the undersigned if there are any additional issues to discuss.

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Respectfully submitted,

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